AUG 2 7 2003

510(k) Summary

K030898

General Information

Classification	Class III (accessory to Class III defibrillator unit)
Trade Name	Mobile Battery Service Station (MBSS)
Submitter	AD Elektronk GmbH Sudentenstrasse 7-9 35583 Wetzlar Germany
U.S. Contact	Richard Tootchen TMS MedTec 33 Steeplechase Drive Turnersville, NJ Tel: (856) 374-8837

Intended Use

The MBSS charging station is used to charge NiCd or SLA batteries of the Lifepak®, Fastpak® and Fastpak 2® series manufactured by Medtronic – Physio Control.

Predicate Devices

Lifepak 12 with Battery Charger – Medtronic-Physio Control	K973486
Lifepak 12 with Battery Charger – Medtronic-Physio Control	K990338

Device Description

The MBSS overall dimensions are 30 cm x 20 cm x 10 cm. It is available either as a table top model or wall mount unit. The table top model has a standard power cord which plugs into a 110 volt wall outlet and non-slip rubberized feet. The wall mount model has a bracket for mounting the charger on a vertical surface. For mounting and use in an automobile (ambulance or rescue vehicle), the wall mount bracket is used. Power

requirements are either standard mains at 120 volts or standard automotive 12 volts.

The charger is only used for charging specific batteries. The batteries are removed from the defibrillator and inserted into the MBSS charging bays. The MBSS is not attached to the defibrillator during operation.

Materials

All materials used in the manufacture of the MBSS battery charger are suitable for this use and have been used in numerous previously cleared products.

Testing

The MBSS is designed to comply with the electrical safety (EN60601-1), electromagnetic compatibility (EN60601-1-2) and UL 60950 standards. The MBSS meets all electrical and EMC requirements.

Testing was conducted to evaluate conformance to the product specification. Testing included:

- Operation of the charger
- Battery recognition
- Charge times
- Appropriate displays
- Impedance
- Electrical safety
- Electromagnetic interference

In all cases, the product test results met specification

Summary of Substantial Equivalence

AD Elektronik believes the Mobile Battery Service Station (MBSS) is substantially equivalent to the predicate products. The intended use, method of operation, methods of construction and materials used, are either identical or substantially equivalent to existing legally marketed predicate products.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 27 2003

AD Elektronic GmbH
c/o Mr. Richard Tootchen
TMS Medical Technologies
33 Steeplechase Drive
Turnersville, NJ 08012

Re: K030898
Mobile Battery Service Station-Model MBSS
Regulation Number: 870.1025
Regulation Name: Arrhythmia Detector and Alarm
Regulatory Class: Class III
Product Code: MKJ
Dated: August 4, 2003
Received: August 6, 2003

Dear Mr. Tootchen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): This application K030898

Device Name: Mobile Battery Service Station (MBSS)

Indications for Use: The MBSS charging station is used to charge NiCd or. SLA batteries of the Lifepak®, Fastpak® and Fastpak 2® series manufactured by Medtronic – Physio Control.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Prescription Use _ 5 OR 5 [illegible] Over-The-Counter Use _
(Per 21 CFR 801.109) (Optional Format ~~1~~-2-96)